However, as discussed below, the device recited in the pending claims is not anticipated by the patent to Nicholson et al. The patent to Nicholson discloses a device and method for confirming the location of a presymptomatic, non-palpable breast lesion by placement and manipulation of a probe. The probe is comprised of a cannula housing a wire. The wire is percutaneously introduced into the fleshy sidewall of a breast whereat it is hoped the distal end lies at about 2 cm from a lesion previously determined by a mammography. The percutaneously inserted probe wire remains as a location marker for invasive surgical excision of the lesion. Also, the percutaneously inserted wire is coated with a silicone or Teflon for purposes of lubricity and electrical insulation.

Both silicone and Teflon, which are disclosed as coatings on the wire, are notoriously well-known in the art for their non-sticking characteristics. More specifically, Teflon is known as "a waxy, opaque material, polytetrafluoroethylene, employed as a coating...to prevent sticking." *The American Heritage Dictionary of the English Language*, Fourth Edition 2000. Similarly, silicone is "characterized by ...high lubricity, extreme water repellence and physical inertness..." *The American Heritage Dictionary of the English Language*, Fourth Edition 2000.

In the Office Action, it is asserted that the Patent to Nicholson discloses a device for collecting breast duct fluid from within a breast duct in order to detect breast cancer. Specifically, the Office Action indicates that the probe wire (12) is disclosed as a device for fluid retrieval from a breast duct. However, no such description appears in the Patent to Nicholson.

In the Patent to Nicholson, the probe wire (12) is a solid structure composed of titanium or a bimetal material with no fluid absorbing capabilities. Nevertheless, it appears that the position has been taken in the Office Action that surface tension would cause some ductal fluid to adhere to the probe wire (12) as the wire is withdrawn from a breast duct. However, the probe

wire is specifically disclosed as being coated with silicone or Teflon, materials that are notoriously well known for their fluid repelling and non-stick characteristics. See col. 2, lines 50-54. Additionally, any fluid alleged to incidentally be resting on the probe wire would be wiped off the wire by the ductal sphincter that closes access to the breast duct in question as the wire is removed from the breast duct through the sphincter. Therefore, the Patent to Nicholson does not disclose a device capable of collecting fluid from a breast duct, much less a device cable of retrieving a sample of breast duct fluid from within a breast duct for analysis.

Further, insertion of the wire into a breast duct through a ductal orifice is not disclosed or contemplated in the patent to Nicholson. First, the shape of the probe wire with its hook does not allow for insertion into a breast duct through a ductal orifice, at least because of the size of the hook relative to a ductal opening. Second, the wire's percutaneous tip, if inserted within a breast duct, could puncture the duct thereby causing it to collapse and causing significant injury to the patient. A person of ordinary skill in the art would recognize the serious potential for injury of a patient by placing a puncturing device, such as the wire of Nicholson, in a breast duct of a body.

For all of the above discussed reasons, the Patent to Nicholson does not disclose the recited device. Additionally, it would not have been obvious to one of ordinary skill in the art to modify the percutaneously tipped hooked wire of Nicholson so that it could receive a ductal fluid sample because no motivation exists for such a modification and such a modification is contrary to the common knowledge of the ordinary artisan.

Claims 1-6 were rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Pat. No. 5,711,309 to Goldenberg. The Patent to Goldenberg discloses an eardrum puncturing device and method for collecting a specimen of middle ear fluid by puncturing the ear drum of a patient. The puncturing device, sized for positioning within a middle ear, comprises a needle and a fluid

absorbent material. The needle possesses a percutaneous tip that is used to puncture the ear drum. Fluid is then absorbed from behind the ear drum by the fluid absorbent material attached to the needle.

The Patent to Goldenberg does not contemplate a method or device other than for the removal of fluid from an ear drum. Further, as discussed above, the device depicted in the disclosure is sized for positioning within the ear canal. The ear canal is significantly larger than the orifice of a breast duct. It is known to those skilled in the art that a single nipple contains at least eight or more ductal orifices that open into respective breast ducts. Additionally, it is well known to those skilled in the art that magnification or vision enhancing devices are commonly used to locate a ductal orifice on a nipple surface, whereas the ear canal is clearly visible to the human eye and is large enough in size to receive a human finger. The size considerations for accessing an ear canal are significantly different from those of a breast duct.

Therefore, contrary to the position taken in the Office Action, the Patent to Goldenberg does not disclose a probe having a diameter sized to penetrate a breast duct, rather it discloses only a much larger device for insertion into an ear canal. As a result, the Applicant asserts that a prima facie case of anticipation has not been set forth because the device disclosed in the Patent to Goldenberg is not sized to penetrate a breast duct through a ductal orifice, pass through the sphincter, contact an interior lumen of a breast duct, and retrieve a sample of the breast duct fluid. Further, the examiner has provided no motivation to combine the disclosed device with other art or to significantly reduce the size of the device as the device was only depicted and disclosed so as to snugly fit in an ear canal. Additionally, one of ordinary skill in the art would not have been motivated to reduce the size of the percutaneously tipped ear drum puncturing

device so that it could fit in a breast duct because the possibility of puncturing the duct and significantly injuring the patient would exist.

Claim 27 was rejected under 35 USC §103(a) as being unpatentable over U.S. Pat. No. 4,616,656 to Nicholson et al.

As discussed above, the patent to Nicholson does not anticipate the device recited in claim 1. Similarly, no motivation or teaching exists in the prior art for modifying the hooked, percutaneously inserted wire of Nicholson to arrive at the device for collecting a ductal fluid sample recited in claim 27. Therefore, it would not have been obvious to one of ordinary skill in the art to modify the hooked, percutaneously tipped wire of Nicholson to arrive at the device recited in claim 27. Withdrawal of the rejection is requested.

For all of the above-discussed reasons, Applicant respectfully submits that claims 1-13, 26 and 27 are allowable and that the application is now in condition for allowance. A notice to this effect is earnestly solicited.

Applicant requests that the finality of the outstanding Office Action be withdrawn because the publications applied in the outstanding rejections have not been previously cited or identified. Also, it is requested that the finality of the Office Action be removed in view of the above-discussed inapplicability of the cited publications.

If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant's attorney, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

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